




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,381	09/09/2004	Hiroshi Kanai	71532	6389
23872 7590 03/09/2007 MCGLEW & TUTTLE, PC P.O. BOX 9227 SCARBOROUGH STATION SCARBOROUGH, NY 10510-9227			EXAMINER FERNANDEZ, KATHERINE L	
			ART UNIT 3768	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/507,381	Applicant(s)  KANAI ET AL.	
	Examiner Katherine L. Fernandez	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/9/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date <u>9/9/2004 and 7/18/2006</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|---|

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed on September 9, 2004 and July 18, 2006 are acknowledged. The information disclosure statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (U.S. Patent No. 4,803,994).

Burke discloses an ultrasonic diagnostic system for measuring differential backscatter across a selected volume of tissue or organ and detecting temporal and frequency dependencies of backscatter in order to distinguish between normal and diseased tissue (column 1, lines 51-55). Their system includes the steps of transmitting ultrasonic pulses to a living tissue, as well as receiving and analyzing the reflected wave of the ultrasonic pulses (column 3, lines 4-25). Further, their system includes a processing unit (15) to measure a backscattering intensity by using a scattering wave from a region of interest in the living tissue on a basis of the reflected wave, and to

detect a variation frequency of the measured backscattering intensity to obtain the diagnostic data to be available (column 2, lines 48-68 through column 3, lines 1-12).

See Figure 1.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Papadofrangakis et al. (U.S. Patent No. 4,217,909).

As discussed above, Burke meets the limitations of claims 1 and 10. However, Burke does not specifically disclose the ultrasonic pulses are transmitted at a high repeated transmission frequency of a few kHz to measure the backscattering intensity. Papadofrangakis et al. disclose a method and ultrasound apparatus for measuring the

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velocity of blood flow (column 1, lines 6-9). Their system includes the use of a transducer element that is excited to generate pulses of ultrasound with a given emission frequency that insonifies the target (column 1, lines 56-64). The pulse repetition frequency settings they used were of a few kHz (column 6, lines 8-17). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Burke's system to have the ultrasonic pulses transmitted at a high repeated transmission frequency of a few kHz to measure the backscattering intensity. The motivation for doing so would have been to achieve the desired velocity resolution, as taught by Papadofrangakis (column 6, lines 12-15).

7. Claims 3-5, 7-9, 12-14, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Kanai et al. ("Real-time Measurements of Local Myocardium Motion and Arterial Wall Thickening", September 1999).

Regarding claims 3-5 and 12-14, as discussed above, Burke meets the limitations of claim 1 and 10. Burke's system includes a processing unit (15) that has means for calculating the backscatter intensity from signals provided from a signal processor (13) (column 2, lines 48-62). See Figure 1. Further, Burke discloses that their system detects the variation frequency of the backscattering intensity (column 2, lines 61-68 through column 3, lines 1-3). However, they do not specifically disclose that the analytical processing unit further comprises means for calculating a displacement waveform of the region of interest by applying a phased tracking method to the reflected signal that is received, nor that the backscattering intensity is calculated from the displacement waveform. Kanai et al. disclose the phased tracking method for tracking

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the movement of the heart wall and arterial wall (abstract). Further, they disclose that the phased tracking method is applied to the reflected ultrasonic pulse and is used to calculate the phase change, average velocity, and displacements (pg. 1231, 2nd column, 4th paragraph – pg.1232). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the system of Burke to have the processing unit calculate a displacement waveform by applying a phased tracking method to the reflected wave signal. The motivation for doing so would have been to accurately detect small velocity signals, as taught by Kanai et al. (pg. 1230, column 2, 2nd paragraph).

Regarding claims 7-9 and 16-18, Burke discloses that their system includes means for displaying the backscatter intensity or any other backscatter feature for presentation on a display (17) in any desired format (column 2, lines 61-64). See Figure 1. However, they do not specifically disclose that the instantaneous thickness variation velocity of the region of interest on the basis of the variation frequency of the variation cycle of the detected backscattering intensity is displayed, nor that it has a function for converting the variation frequency or variation cycle of the backscattering intensity into a suitable color or density level according to a predetermined color bar or gray scale superimposed on an M-mode image. Kanai et al. disclose that the velocity signals and change in thickness can be calculated and displayed (pg. 1236-1237, Section VI). Also see Figure 7. They also disclose that they superimpose their results on the M-mode image using a color code (pg. 1231, 1st column, 1st paragraph, and see Figure 5(a)). At the time of the invention, it would have been obvious to a person of ordinary skill in the

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art to display the instantaneous thickness variation velocity of the region of interest, as well as to convert the variation velocity or variation cycle into a suitable color, superimposed on an M-mode image. The motivation for doing so would have been to be able to provide means for quantitative analysis, and to evaluate the accuracy and performance of the system, as taught by Kanai et al. (abstract and pg. 1238, 2nd column, 2nd paragraph).

8. Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Kanai et al (Sept. 1999, from now on referred to as Kanai_1999) as applied to claims 3-5, 7-9, 12-14 and 16-18 above, and further in view of Kanai et al. ("Noninvasive Evaluation of Local Myocardial Thickening and Its Color-coded Imaging", July 1997, from now on referred to as Kanai_1997).

As discussed above, the combined references meet the limitations of claims 5 and 14. However, they do not specifically disclose that the variation frequency of the backscattering intensity is frequency of tens to hundreds of Hz. Kanai_1997 disclose a method for tracking the movement of the heart based on the acoustic characteristics of the heart muscle (abstract). Their method involves transmitting ultrasonic pulses from an ultrasonic transducer on the chest surface, and then performing calculations on the ultrasonic pulse reflected from the object (pg. 753-755, Section II). Further, they disclose that the measurable frequency band is from d.c. to several hundred Hz (pg. 765, 2nd column, 2nd paragraph). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have the variation frequency of the backscattering intensity be of a frequency of tens to hundreds of Hz. The motivation for

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doing so would have been that in previous studies, the measurable frequency has been within these limits, as taught by Kanai_1997 (pg. 765, 2nd column, 2nd paragraph).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SPE ART UNIT 3768